Petition

Reply to Office Action Summary, This action is non-final

Applicant: Shin-Jen Shaio

Application No.: 10/554,315

Filed Date: 10-24-2005 Group Art Unit: 1614

Attorney Docket No.: Examiner: THOMAS, TIMOTHY P

Confirmation No.: 2698

To the Commissioner of Patents:

The applicant was notified by The Examiner about Office Action Summary mailed on 07/12/2011, and the period for reply is set to expire 1 month from the mailing date of this communication.

The applicant had filed on Aug. 17, 2010 a petition reply to Office Action summary in which had attached the original translation of PCT's description for the reference of the Examiner stated:

"To allow reinstating the description of application, but not claims.

The published description of application which done by the former attorney, Chauncey Johnson, was very rough and poor not only omitting many contents of the application but also done many mistakes in that. This content was not complete, especially, omitting some acids such as succinic acid, acetic acid, phosphoric acid and their acidic salts in TABLE-US-00002 of section [0081]. So the petitioner courteously asks the Examiner that allows the petitioner to amend as the content filed in PCT." So does in the amendment of description.

In response to the Office Action Summary

1. A general principle of the invention

There are few paragraphs of Examination Guidelines for Patent Applications relating to Medical Inventions in the UKIPO 2008, wherein the second medical use claims- the substance or composition maybe concerning the invention now. In assessing novelty and invention step, in paragraph 145 it says: However, if the specification discloses a general principle capable of general application, a claim in correspondingly general terms may be acceptable. There is no need to show poof of its application in every individual possible instance which could fall within the scope of the claim. This principle is of course, applicable to more than just second medical use claims, but is particularly important for such claims are defined by the purpose of product.

The general principle of the invention is supplying protons in body fluid by administering edible acid. Protons are generic factors, which released from carboxyl function group, phosphoric acid, or gluconolactone which when it being

dissolving in water to form gluconic acid, and lowering the humoral pH, by which causes the treatment ailments finally. This general principle of the invention is fully supported by the description of present application. This general principle was demonstrated in testing the rate of inhibiting histamine, the main factor of hypersensitivity diseases, in examples of [0081] TTABLE-US-00002 for testing of histamine inhibition using 100% of each compound in each experiment. There are 1-32 examples. All these acids used have the same property of releasing the same protons, lowering the humoral pH and shown the same results of inhibiting histamine. Accordingly, carboxylic structure or protons releasing structure contained acids are the generic compounds (or derivatives) which are acceptable by paragraph 145 of Second use medical guidelines, because there are disclosures in the description enabling the skilled person to decide which of other carboxylic acids would have so worked.

In the other words, it is the common principle that all edible acids claimed show the same treating properties. No matter what kind of carboxylic acid or phosphoric acid claimed in claims all of them are doing the same simplest reaction of releasing protons, lowering humoral pH and forming protonation between histamine and protons. All the carboxylic acids or phosphoric acid treat the same ailments by the same protons being a general principle of the invention. That is the core principle of the invention. Just as concerning the capability of controlling the activities of histamine, even though in other exemplified embodiments there is some ailments treated only by one kind of carboxylic acids or phosphoric acid in examples, it is also reasonable to consider that other carboxylic acid or phosphoric acid would do the same work of that ailment treatment. That evidence was improved by the facts shown in the examples [0081] TTABLE-US-00002 of the specification, different carboxylic acids or phosphoric acid all shown the same effect in treating allergy ailments which could fall within the scope of the claim. Accordingly, only one carboxylic acid testing for one kind of ailment would apply to other carboxylic acids or phosphoric acid. Therefore, there is no way to elect any more. Also all acid or phosphoric acid species being encompassed in claims were identified according to paragraph 145 of Second use medical guidelines.

The applicant suggests courteously that would the Examiner please assessing the support for the invention by a new concept but not by the traditional concept of one compound only for one kind ailment, because the way of disease treatment is completely different from the traditional method. In all biochemical reactions, including diseases, are taking place in a defined pH value, says in a little basic condition of pH 7.4 which could be affected by the addition of protons completely, and inducing a result of ailment treatment. These findings concern a nature biochemical reaction of disease treatment and completely against the traditional concept of drug treatment. To the best knowledge of the applicant that findings is first found by the applicant and apply to treat diseases.

There is a nature evidence which happens in our body could be applied to support this invention. It is well known that after a hard working of muscles, violent

and repeating endure exercise for a long period of time, a large amount of lactic acid is formed in that part of body. Normally, scientists explain that is the product of the oxidation of glucose in a condition of insufficient of oxygen. But, they did not pay attention to the fact that natural immune and defence of our body. After violent and repeating endure exercise, there were a large amount of dead cells and injured structure of muscles caused in the body. Those dead cells and injured structure of muscles would be recognized as antigens in our body by immune reaction. In generally condition, a great amount of histamine should be produced and causing bad inflammation in that part by immune reaction. Why not? That is because the lactic acid formed can release protons which show the ability of inhibition of histamine's reactions. To apply this nature alleviation and cure of diseases is the main innovation of this invention.

2. The prior art Ohashi, et al. (US 6,297,244B1) is not concerning the invention.
The referred prior art as its abstract says: A stabilized pharmaceutical composition comprising
(R)-2-(4-bromo-2-fluorobenzyl)-1,2,3,4-tetrahydropyrrolo[1,2-a]pyrazine-4-spiro-3'-pyrrolidine-1,2',3,5'-tetrone (hereinafter, referred to as "AS-3201") and as a stabilizer at least one acidic substance having an acidity more potent than that of AS-3201, such as ascorbic acid, citric acid, tartaric acid, lactic acid, maleic acid, malic acid or phosphoric acid. Therefore, even though they contain some of acids, they are used as a stabilizing agent for "AS-3201", and do not concern any treatment of ailment at all. The claims of the invention claim to lower humoral pH and treat ailments.

3. The abstract is amended.

4. Amendments in description:
The description filed in national phase by the former attorney was very bad not only with many mistakes but lacked many content which would not meet to support the claims readable. That the applicant amended the whole description based on the original PCT. There are not new items being added but correcting some mistyping. Because the area of amendment was so wide, as shown in following item of (1), that the applicant replaces the whole description with versions of a marked and a clean one.
(1). Sections of [0001], [0003], [0003-1], [0004], [0007], [0008], [0015], [0015-1], [0015-2], [0015-3], [0015-4], [0016], [0019], [0020], [0023], [0029], [0030], [0031], [0038], [040], [0041-1], [0041-2], [0041-3], [0041-4], [0044], [0045], [0053-1], [0054], [0056], [0063], [0066], [0071] (10-1), (10-2); [0075], [0079], [0083], [0086-1], [0091], [0093-1], [0093-2], [0093-3], [0096-1], [0096-2], [0096-3], [0097-1], [0097-2], [0097-3], [0100], [0102-1], [0102-3], [0106-1], [0106-2], [0106-3], [0106-4], [0106-5], [0106-6], [0106-7], [0106-8], [0106-9], [0106-10], [0106-11], [0106-12], [0106-13], [0106-14], [0106-15], [0108],

[0114-1], [0114-2], [0114-3], [0114-4], [0114-5], [0114-6], [0114-7], [0117], [0117-1], [0120], and [0124] are amended.

(2). In [0044] there are four acids(phosphoric acid, acetic acid, propionic acid and succinic acid) are added, in which they are all original acids, but succinic acid is mistyping. The evidences are shown in Table 2 original example (4), [0091], [0093], [49-1],

(3). In TABLE-US-2 (10-1) succinic acid 9.00 100 is amended. The succinic acid was original in Table 2 and in the sections of [0091] and [0093]. As for maleic acid although did not in the original Table 2, but has been used as effective component in [0088] and [014-2]. On top of that in TABLE-US-2 [0071] there were (10-16) sodium hydrogen maleate 9.00 100 (10-17) potassium hydrogen maleate 9.00 100, but did not have the compound of maleic acid. It is obviously that there was mistyping in loss of maleic acid. There are other evidences to prove that. The acidic salts of sodium and potassium of maleic acid show good drug depression effect of histamine. Then the maleic acid itself should do the same testing reaction better than its acidic salts. This amendment is not beyond the scope of description of the invention

5. Amendments in claim:

The applicant select number (3) "A product, a process specially adapted for the manufacture of the said product, and a use of the said product" for multiple categories of invention which the Examiner constructed.

(1). Because of the generic effect of protons which inducing lower the humoral pH by which cause the ailments finally. This general principle of the invention is fully supported by the description of present application as mentioned hereinabove. The applicant divided many groups of claims by which in order to avoid the prior arts of disclosed searched by PCT office. As shown in the separated sheets. This amendment is not beyond the scope of description of the invention

(2). Claim 66 in which the term of suspension is read in [0093] of emulsion, because the particle of emulsion being suspended in other phase.

(3). Claim amendment is shown in separated sheets.

Yours faithfully,

Shin-Jeh Shaio

Augest 02, 2011

Attachments:

1). Amended abstract in marked version
2). Amended abstract in clean version
3). Amended description in marked version
4). Amended description in clean version.

5). Amended claims in marked version
6). Amended claims in clean version.